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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,836

Applicant(s)

BETT ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 10-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to amendment filed 27 December 2004.

Claims 1-15 are under consideration.

Claim Objections Maintained

Claims 10- 15 re objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims 10-13 depend on a claim that is a nucleic acid.

The claims have been amended to recite a nucleic acid comprising a helper virus.

This is not sufficient to overcome the objection.

It is suggested that the claims recite something to the effect of "the low homology packaging cassette of claim 1 further comprising [elements for use as a helper virus].

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1- 15 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants arguments are persuasive and the rejection is withdrawn.

Claim Rejections - 35 USC § 102

Claims 1- 5, and 7 were rejected under 35 U.S.C. 102(b) as being anticipated by Hardy (WO97/32481).

The rejection is withdrawn.

Claims 6, 8, and 9- 12 were rejected under 35 U.S.C. 102(b) as being anticipated by Hardy.

The rejection is withdrawn.

New Rejections

Claim Rejections - 35 USC § 102

Claims 1-5, 7, and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardy (WO97/32481) in light of Grable *et al.* (1990, IDS).

The claims are drawn to a nucleic acid comprising a low homology packaging signal cassette. The dependent claims add loxp, frt, packaging is less efficient, wild type is Ad5, maximum 23 contiguous base pairs homology to wild type, and the nucleic acid is a plasmid, is a helper virus, does not contain an E1 gene, and has an insert of about 2.9 kb in the E3 region.

Hardy teaches synthetic low homology packaging cassettes are useful because they are less efficiently packaged and teaches the synthetic six repeated A elements as a preferred synthetic packaging signal and the adenovirus is type 5 (page 20, lines 22-29). The synthetic six repeated A elements of Grable *et al.* 1990 (disclosed in Hardy) contain the synthetic A repeat (six times) in a Ad vector that is deleted in the packaging region. The repeated A repeat of Grable *et al.* is 24 bases and the packaging region is deleted (Figure 3 of Grable *et al.*). The 6 A repeat low homology packaging signal of Hardy meets the definition of low homology as stated on page 4 of the specification because it has 25 bases or less contiguous homology with wild type.

Hardy teaches using recombinases Cre and Flt (recognition sites are loxp and frt)(see at least pages 8-9 and Figure 4). The virus of Hardy would be expected to be 2-3 times less efficient because it has the same structure as required by the claims.

These constructs can be plasmids, can contain deletion of E1, and can be a helper virus (page 20, lines 16- 20). Hardy teaches an adenovirus with an E1 deletion can accommodate an insertion of about 2.9Kb in the E3 region because Hardy describes a helper virus with an insert which is about 2.9Kb (Ad-betaGal in example 1).

This rejection is modified from a previous rejection and Applicant's arguments are addressed.

Applicant argues limitations that are in the supplemental response which was not entered.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

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(i.e., the variable portions of the A elements and switching of A elements) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is also noted that these features are not in the definition on page 4 for "low homology".

Thus, Hardy anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4- 6, 8, and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hardy (WO97/32481) in light of Grable *et al.* (1990, IDS) and Schmid *et al.* (J Virol 1997, from IDS).

Claims 1-5, 7, and 9-12 are discussed in the immediately previous rejection of Hardy in view Grable *et al.*

The limitations in the additional claims are as follows: 23 bp contiguous sequence, SEQ ID# 1, no promoter in insert, and an insert with at least about 2.7Kbps with no promoter.

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Hardy is discussed above.

Hardy does not teach a maximum of 23 bps contiguous sequence or SEQ ID# 1.

Schmid *et al.* teach the A repeat of SEQ ID# 1 and it is 23 bps or less (Figure 4).

One of ordinary skill in the art at the time of invention would have been motivated to use the corrected A repeat sequence of Schmid *et al.* in the low homology packaging cassette of Hardy because this was shown to be the consensus sequence of the packing motif. One of ordinary skill in the art at the time of invention would have known to not use a promoter with the insert if it were not expressed or if it was intended to be driven off another promoter. One of ordinary skill in the art at the time of invention would have been motivated to use introns because these sequences are normally excised like they would be in the vector.

Thus, it would have been prima facie obvious to modify the A elements of Hardy with the more correct sequence of A repeat of Schmid *et al.* with the expectation of success because the motif is shown to be the actual consensus.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Myron G. Hill
Patent Examiner
15 April 2005



JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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